

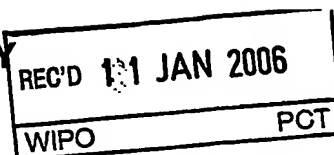
## PATENT COOPERATION TREATY



PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)



|   |  |  |  |
|---|--|--|--|
| Applicant's or agent's file reference<br>PWO051578  |  | FOR FURTHER ACTION   | See Form PCT/PEA/416                         |
| International application No.<br>PCT/US2004/038405  |  | International filing date (day/month/year)<br>12.11.2004   | Priority date (day/month/year)<br>13.11.2003 |
| International Patent Classification (IPC) or national classification and IPC<br>B65D5/38, B65D5/50  |  |  |  |
| Applicant<br>MEADWESTVACO CORPORATION et al.  |  |  |  |
| <p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 7 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau) a total of 17 sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the International application as filed, as indicated in Item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> |  |  |  |
| <p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>  |  |  |  |
| Date of submission of the demand<br><br>13.09.2005  |  | Date of completion of this report<br><br>11.01.2006  |  |
| Name and mailing address of the International preliminary examining authority:<br> European Patent Office - P.B. 5818 Patentlaan 2<br>NL-2280 HV Rijswijk - Pays Bas<br>Tel. +31 70 340 - 2040 Tx: 31 651 epo nl<br>Fax: +31 70 340 - 3016   |  | Authorized Officer<br><br>Sundell, O<br><br>Telephone No. +31 70 340-3628<br> |  |

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**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/US2004/038405

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**Box No. I Basis of the report**

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1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

**Description, Pages**

|                 |  |
|-----------------|--|
| 1, 2, 4, 10, 11 | as originally filed                              |
| 3, 3a-3d, 5-9   | received on 18.10.2005 with letter of 11.10.2005 |

**Claims, Numbers**

|      |  |
|------|--|
| 1-24 | received on 18.10.2005 with letter of 11.10.2005 |
|------|--|

**Drawings, Sheets**

|     |  |
|-----|--|
| 1-3 | received on 18.10.2005 with letter of 11.10.2005 |
|-----|--|

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):
4. ☒ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
  - ☒ the claims, Nos. 1
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/US2004/038405

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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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**1. Statement**

|                               |             |                |
|-------------------------------|-------------|----------------|
| Novelty (N)                   | Yes: Claims | 1-7,9-17,19-24 |
|                               | No: Claims  | 8,18           |
| Inventive step (IS)           | Yes: Claims | 5              |
|                               | No: Claims  | 1-4,6-24       |
| Industrial applicability (IA) | Yes: Claims | 1-24           |
|                               | No: Claims  |                |

**2. Citations and explanations (Rule 70.7):**

**see separate sheet**

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement**

1. Reference is made to the following document:  
D1: GB-A-1 042 429 (THE FORGROVE MACHINERY COMPANY LIMITED) 14  
September 1966 (1966-09-14)

The document:

D3: US-B1-6 230 893 (WESTVACO CORPORATION) was not cited in the international search report. A copy of the document is appended hereto.

2. The following subject matter in claim 1 goes beyond the disclosure as originally filed:  
"when the extension panel (120) is folded inwardly of the outer sleeve (100) the aperture (144) forms a second engaging edge (146) complementary to the first engaging edge (154) to prevent detachment of the slide ~~and form card (10) from~~ [sic] the outer sleeve". No engagement of complementary edges is disclosed in the original application. Consequently claim 1 has been treated as explained below:

It is furthermore not clear how "when the extension panel (120) is folded inwardly of the outer sleeve (100) the aperture (144) forms a second engaging edge (146) complementary to the first engaging edge (154)" (to prevent detachment of the slide ~~and form card (10) from~~ [sic] the outer sleeve, lines 10-11 of claim 1). It appears that it is rather the edge 152 and the fold between the panels 16 and 22 that achieve this (or edge 154 and the fold between the panels 108 and 120). Therefore, inventive step is objected below, the stopping feature interpreted as explained above. However, the wording below still reflects the present claim 1.

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 does not involve an inventive step in the sense of Article 33(3) PCT.

The document D1 is regarded as being the closest prior art to the subject-matter of claim 1, and discloses a device for receiving and securing an item, the device

comprising a slide card (12, Fig. 5) and a tray receiving area, a preformed tray (10) configured to receive and hold a portable item (page 1, line 41, pocket 11), which tray is attached to the tray receiving area (page 1, lines 42-43), an outer sleeve (20) configured to receive the slide card and attached tray and comprising a plurality of side panels.

The subject-matter of claim 1 therefore differs from this known device in that it comprises features preventing detachment of the slide from the outer sleeve.

The problem to be solved by the present invention may therefore be regarded as that the sleeve may become separated from the slide card and consequently lost.

This problem has been solved in document D3 (column 2, lines 16-19) by incorporating into a slide card (100) an engaging element (106) including a first engaging edge and said slide card cooperating with an outer sleeve (50) comprising first and second side panels (10, 26) in face contacting relationship (column 3, line 57-59), wherein an extension panel (4) is hinged to an edge of the first side panel (10) adjacent a third side panel (18), wherein an aperture (12) common to both of the first side panel (10) and the extension panel (4) is sized and arranged such that when the extension panel (4) is folded inwardly of the outer sleeve (50) the aperture (12) forms a second engaging edge complementary to the first engaging edge preventing detachment of the slide and from the outer sleeve. (\*The words "and from" were interpreted as card from)

The skilled person would regard it as obvious to incorporate these features to the sleeve and slide card of D1, to solve the problem posed, thus arriving at the subject matter of claim 1. The subject matter of claim 1 is therefore not inventive (Article 33(3) PCT).

3. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 8 is not new in the sense of Article 33(2) PCT.  
Document D1 discloses (the references in parentheses applying to this document):

Device suitable for receiving and holding an item, comprising a slide card (12, Fig.5) constructed of a first material (side 1, lines 68-69), comprising at least a first panel

(cf. Fig.5) and at least one tray receiving area located on said first panel, at least one pre-formed (page 1, line 39) tray (10) constructed of a second material (page 1, lines 39-40) and comprising at least one receiving recess (11), attached to said card (12) at said tray receiving area and, an outer sleeve (20) defining a void, comprising an open end configured to permit said card (12) and attached tray (10) to translate in and out of said void.

The subject matter of claim 8 is therefore not new (Article 33(2) PCT).

4. The present application does not meet the criteria of Article 33(1) PCT, because the subject matter of claims 13 and 21 does not involve an inventive step in the sense of Article 33(3)PCT.

Document D1, which is considered to represent the most relevant state of the art to the subject matter of claim 1, discloses a slide card, tray and outer sleeve (cf. Fig. 5) from which the subject matter of claim 13 differs in that it discloses means for engaging, means for locking said engaging means and means for releasing said means for locking.

The problem to be solved by the present invention may therefore be regarded as the combination tray and slide card is not child resistant.

The person skilled in sleeved cartons would regard it as obvious to use the locking and release elements of D3 (cf. D3, column 1, line 44 - column 2, line 3) in the sleeve of D1 to solve the problem posed. The proposed solution in independent claim 13 cannot therefore be considered inventive (Article 33(3) PCT).

The same reasoning applies, *mutatis mutandis*, to the subject-matter of the corresponding independent claim 21, which therefore is also considered not inventive.

5. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 18 is not new in the sense of Article 33(2) PCT.

Document D1 discloses (the references in parentheses applying to this document):

Foldable tray card (12) formed of contiguous panels (cf. Fig.4), comprising an engaging panel (14, together with the spine panel) defined by a first edge and spaced apart hinge, a second panel (between panels 13 and 14) defined by said hinge and a spaced apart second edge, a tray (10) integral to said second panel, at least one receiving recess (11) located within said tray (10), a third panel (13) hingedly attached to said second edge folding over and covering said recess.

The subject matter of claim 18 is therefore not new (Article 33(2) PCT).

6. Dependent claims 2-4, 6, 7, 9-12, 14-17, 19, 20 and 22-24 do not contain any features which, in combination with the features of at least some of the claims to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, see document D1 and the corresponding passages cited in the search report, and document D3.
7. Although drafted as such, claim 5 is not a dependent claim in the sense of Rule 6.4(a) PCT, because the subject matter of claim 5 does not comprise a slide card comprising an engaging element, and thus claim 5 does not include all the features of claim 1. Claim 5 is therefore treated as an independent claim.

The prior art does not have clear teaching to place an engaging element on a tray as described in claim 5. The current invention solves the problem of providing an alternative to the prior art. This solution is not suggested by the available prior art. The subject matter of claim 5 is therefore new and may be considered to involve an inventive step (Article 33(2) and (3) PCT).

attached to either the card or tray configured to connect with similar elements associated with the outer sleeve, and referred to herein as the means for locking. The means for releasing include panels, tabs, ribs, abutments, edges, cutouts, catches, apertures, and like elements, integral to or attached to the outer sleeve, configured to uncouple engaged or locked elements. Thus, the present invention provides an optional child resistant feature. A means for stopping comprise panels, tabs, ribs, catches, abutments, apertures, edges, cutouts and like elements, integral to or attached to either the card or the tray, configured to matingly engage similar elements associated with the outer sleeve. Thus, the present invention provides an optional spill-resistant feature to prevent the user from pulling the tray completely away from the outer sleeve.

According to a first aspect of the invention, there is provided an apparatus for receiving and securing an item, the device comprising a slide card having an engaging element including a first engaging edge and a tray receiving area, a pre-formed tray attached to the tray receiving area, configured to receive and hold a portable item, an outer sleeve configured to receive the slide card and attached tray, said outer sleeve comprising a plurality of side panels wherein a first side panel is configured to be in face contacting relationship with a second side panel, said first side panel being provided with an extension panel hinged to an edge adjacent the third side panel, wherein an aperture is struck from the first side panel and the extension panel, the aperture being sized and arranged such that when the extension panel is folded inwardly of the outer sleeve the aperture forms a second engaging edge complementary to the first engaging edge, to prevent detachment of the slide card from the outer sleeve.

Preferably, the apparatus comprises a locking element configured to connect with the element at a locking position and release element integral to said outer sleeve, configured to disconnect said engaging element from said locking element to permit the slide card to be at least partially withdrawn from the outer sleeve.

Preferably, the card is constructed of a first material and said tray is constructed of a second material.

Preferably, the second material is plastic.

Preferably, the engaging element is positioned on said tray.

Preferably, the tray comprises at least one receiving recess configured to receive and hold said portable item.



3a

Preferably, the outer sleeve further comprises an interior aperture configured to connect said engaging element at a stopping position.

According to a second aspect of the invention there is provided an apparatus for receiving and holding an item; comprising:

a slide card constructed of a first material, comprising at least a first panel and at least one tray receiving area located on said first panel;

at least one pre-formed tray constructed of a second material and comprising at least one receiving recess, attached to said card at said tray receiving area; and an outer sleeve defining a void, comprising an open end configured to permit said card and attached tray to translate in and out of said void.

Preferably, the slide card further comprises an engaging element connected to at least one of said first panel and said tray.

Preferably, the outer sleeve further comprises a locking element configured to releasably connect to said engaging element at a locking position.

Preferably, the outer sleeve further comprises a release configured to disconnect said engaging element from said locking element.

Preferably, the outer sleeve further comprises a stopping element configured to connect to said engaging element at a stopping position.

According to a third aspect of the invention there is provided an apparatus for receiving and securing an item comprising:

a slide card comprising means for engaging and at least one tray receiving area:

at least one pre-formed tray, attached to said tray receiving area, configured to receive and hold at least one portable item;

an outer sleeve defining a void configured to receive said card and attached tray, comprising an open end and means for locking said means for engaging; and, means for releasing, integral to said outer sleeve, configured to disengage said means for engaging from said means for locking.

Preferably, the means for engaging comprises an element positioned on at least one of said card and said tray configured to cooperatively connect with said means for locking.

3b

Preferably, the means for locking comprises an element positioned within said void configured to cooperatively connect with said means for engaging.

Preferably, the means for releasing comprises a mechanism positioned along the exterior of said outer sleeve and proximate to said locking element.

Preferably, the apparatus further comprises a means for stopping.

According to a fourth aspect of the invention there is provided a foldable tray card formed of continuous panels, comprising:

an engaging panel defined by a first edge and spaced apart hinge;

a second panel defined by said hinge and a spaced apart second edge;

a tray integral to said second panel;

at least one receiving recess located within said tray, configured to receive and hold an item; and

a third panel hingedly attached to at least one of said second edge and said tray; configured to fold over and cover said item.

Preferably, the panels and said tray are constructed using a thermo-forming process.

Preferably, the panels and said tray are constructed using an injection moulding process.

According to a fifth aspect of the invention there is provided a method of resisting access to an item, comprising the steps of:

providing a slide card comprising a base panel attaching a pre-formed tray comprising at least one recess to said base panel;

providing a means for engaging associated with at least one of said card and said tray;

placing an item in said receiving recess;

providing an outer sleeve with an open end and adjacent void, said sleeve further comprising a means for locking;

aligning said card with said open end;

3c

orienting said means for engagement with said means for locking; and

inserting said card an tray fully into said void;

causing said means for engaging and said means for locking to releasably connect.

Preferably, the step of providing an outer sleeve further comprises providing an outer sleeve having means for releasing, said means for releasing configured to disconnect said means for engaging and said means for locking.

Preferably, the method further comprises the step of manipulating said means for releasing to withdraw said tray at least partially from said void.

Preferably, the method further comprises the step of withdrawing said item from said recess.

**[00011]** Alternative embodiments include an apparatus and method for holding and storing drug delivery devices by providing an inner tray configuration that, by way of example and not limitation, protects a plunger from inadvertent activation; shields a needle from inadvertent exposure; allows easy access to a drug-filled container for removal and replacement; and collects and stores the spent devices. Accordingly, embodiments of the present invention provide an apparatus and system that is able to safely ship drug delivery devices for trans-epidermal, oral, or hypodermic administration, including pre-filled syringes, needles, vials, ampoules, protective shields, patches, inhalers, and parts thereof, and like devices, safely store the unused devices, and safely store the used devices until all can be safely disposed as unit.

**[00012]** Embodiments include a pre-formed tray attached to a paperboard card, and a monolithically formed card/tray combination. Compliance information or general information related to the medication or therapy may be positioned on or with the slide card, tray, or outer sleeve in a manner easily visible by the user. In one embodiment, indicia — such as, but not limited to, time of day, days of the week, numerical sequence, or dosage amounts — are positioned adjacent to the devices.

**[00013]** Another embodiment of the present invention comprises a slide card with an engaging tab and a tray receiving area. At least one pre-formed tray, configured to receive and hold at least one portable item, may be attached to the tray receiving area. An outer sleeve that receives the card and attached tray comprises a locking edge configured to engage the tab at a locking position. The outer sleeve also has an integral release configured to disengage the

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3d

tab from the locking position. Yet another embodiment of the present invention includes a slide card constructed of one material, with a base panel and a tray receiving area located on the base panel. A pre-formed tray constructed of a different material, with at least one receiving recess, is attached to the card at the tray receiving area. Both may be fully inserted within a

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portable goods. Small electronic components, jewelry, foods, expensive and precious articles, and any other item that requires a safe, stable, and portable environment in which to be shipped and stored may find an application with the present invention. Other advantages of the present invention will be apparent from the following description, the accompanying drawings, and the appended claims.

### BRIEF DESCRIPTION OF THE DRAWINGS

[00018] FIG. 1 is an isometric view of a completely constructed embodiment of the present invention.

[00019] FIG. 2 is a plan view of an embodiment of a slide card blank;

[00020] FIG. 3 is a plan view of an alternative embodiment of an outer sleeve blank;

[00021] FIG. 4 is a plan view of an embodiment of a pre-formed tray;

[00022] FIG. 5 is a plan view of an alternative embodiment of a pre-formed tray;

### DETAILED DESCRIPTION OF THE INVENTION

[00023] As required, detailed embodiments of the present invention are disclosed herein. It will be understood that the disclosed embodiments are merely exemplary of the invention that may be embodied in various and alternative forms. The figures are not necessarily to scale, and some features may be exaggerated or minimized to show details of particular components. In other instances, well-known materials or methods have not been described in detail in order to avoid obscuring the present invention. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but as a basis for the claims and for teaching one skilled in the art to variously employ the present invention.

[00024] Referring now to the drawings, wherein like numerals represent like features throughout, there are illustrated embodiments of the present invention. Turning first to FIG. 1 and FIG 2, there is shown an internal slide card 10 and slide card tray 12. As shown, the slide card 10 is configured to connectedly receive the tray 12 at a tray receiving area 14 and the tray 12 is configured to receive and store an item, such as a drug delivery device.

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[00025] Herein, the phrase "drug delivery devices" is used broadly to refer to all apparatus and parts thereof used in conjunction with transferring substances into or out of a body, such as but not limited to a human being. By way of example and not limitation, a drug delivery device comprises a substance in the form of, or contained within, pills, tablets, chewables, aerosols, inhalers, trans-dermal patches, suppositories, injectable devices, parts thereof, and the like. Injectable devices comprise a plunger, barrel, and needle used by a medical professional to treat a patient with a pharmaceutical drug, or the patient to treat him or herself. For purposes of teaching and not limitation, the illustrated tray embodiments are directed to drug delivery devices in the form of injectable devices, but those skilled in the art will immediately understand that the tray may be configured to hold any portable item.

[00026] As best shown in FIG. 1, the illustrated card 10 includes a base panel 16, spine panel 18, top panel 20 and tab 22. The respective panels are defined by fold-lines 24a, b. Depending upon the material used to construct the card, fold-lines are formed by scores, cuts, bends, perforations, live hinges, formed hinges, and the like. As described in detail below, tab 22 may function as part of a means for locking and/or as part of a means for stopping by cooperatively engaging with a first element to create a child-resistant feature or cooperatively engaging with a second element to create a spill-resistant feature.

[00027] With regard to choice of materials, the slide card 10 may comprise paper, paperboard, cardboard, plastic, or combinations thereof. Where the slide card 10 comprises paperboard, bleached sulphate, solid unbleached sulphate, or clay-coated newsback are well-known design choices. Typically the paperboard coating is a fluid blend of materials, such as coating clay, calcium carbonate, and/or titanium dioxide with starch or adhesive smoothly applied to the travelling surface. Successive densification and polishing finish the mineral-coated surface to a superior, graphic-print surface. When the card and/or tray is paper, fabrication techniques well known to those skilled in the art, including vacuum forming, are contemplated. When the card and/or tray is plastic, fabrication techniques well known to those skilled in the art, including thermo-forming, injection molding, and the like, are contemplated. Where the slide card 10 is plastic, the fold-lines 24a, b may be live hinges, or, as explained below regarding the engaging feature of the tab 22, fold-line 24b may be a formed hinge with an upwardly or downwardly extending profile to create an internal spring tension that urges the tab 22 back toward a relatively relaxed or horizontal orientation when the tab 22 is first folded over toward base panel 16.

[00028] FIG. 4 and FIG. 5 show two possible alternative embodiments of pre-formed trays 12, 26. Here, both trays 12, 26 are constructed of plastic, in the manner well known by

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those skilled in the art, and are configured to receive and hold various items of various shapes. Also, as understood by those skilled in the art, both the exterior and interior tray configurations are merely design choices. Here, for purposes of teaching and not limitation, the exterior of the illustrated trays 12, 26 are configured to be affixed to and within the tray receiving area 14 (best shown in FIG. 1), while the interior of the illustrated trays 12, 26 are configured to receive and store drug delivery devices. One drug delivery device illustrated is a vial 30 for holding a medicament in liquid form and another is a syringe 32 to be used in conjunction with the vial 30.

[00029] The tray 26 is configured to receive and store items of substantially uniform shape and size, such as the illustrated syringe 32 comprising a plunger 34, barrel 36, finger guard 38, and needle 40. The tray 26 comprises a means for securing and holding the syringe 32, such as the plunger-receiving recess 42, barrel-receiving recess 44, and needle-receiving recess 46. The recesses 42, 44, 46 may be configured to lock in or otherwise secure the item by including a means for resisting removal such as fold-over locking flaps, indentions, straps, inserts, and the like (not shown). Accordingly, a means for holding and storing a drug delivery device includes a pre-formed tray that can be configured in a variety of ways.

[00030] Regarding the illustrated embodiments, in practice the tray 12, 26 is pre-formed separately and then affixed to the card 10 at the tray receiving area 14, the location being merely a design choice. An alternative embodiment that is not illustrated comprises a monolithically formed card/tray combination. There it is contemplated that the slide card 10 is an integral part of the tray 12, 26, the two components being formed as a single unit during fabrication.

[00031] The tray 12 is configured to receive and store items of substantially unique shapes and sizes, such as the vial 30 and syringe 32. Thus, tray 12 comprises a means for securing and holding the vial 30, such as the vial-receiving recess 48, and a means for securing and holding the syringe 32 as described immediately above. The recess 48 may be configured to lock in or otherwise secure the item by including a means for resisting removal such as fold-over locking flaps, indentions, straps, inserts, and the like (not shown). As understood by one skilled in the art, the various recesses illustrated herein may be configured to receive and store any portable items of any shape or size.

[00032] Here the trays 12, 26 are also configured to allow for easy access to the items. By way of illustration and not limitation, the devices are arranged so that the end user, who may have limited physical mobility such as arthritis, can retrieve one device without affecting another. As illustrated, orienting the widest portion of the syringe 32 – in this

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example, the finger guard 38 – to take the most space to provide the greatest accessibility is a desirable feature of this embodiment. Such horizontal orienting also provides easy viewing of the devices so the user may easily distinguish between them. Further, such orienting provides ample area to receive graphics. For example, dosage regimen instructions including date, day, and time may be formed on the tray sections between or adjacent to the recesses. Alternatively, the items held on the tray may be as closely packed and aligned as desired.

[00033] Patient and healthcare provider information, such as dose compliance, warnings, and instructions in written form or digital form can be made easily visible or accessible to the user through the ample billboard space found on either side of the panels 16, 20, tab 22, or the components described below.

[00034] Turning now to FIG. 3 and FIG.1, there is shown an outer sleeve 100 for receiving an inner card 10 with tray 12, 26, and the related outer sleeve blank 102. As best shown in FIG.3, the illustrated blank 102 includes side panels 104, 106, 108, spine panels 110, end panels 116, 118 and extension panel 120. The panels 104, 106, 108 are defined by the respective adjacent fold-lines 124a, b and the respective outer edges 126.

[00035] Side panel 104 comprises release button 130, defined by release button cut 132 and release button fold-line 134. Side panel 108 comprises a first engaging tab cutout 140 defined by cut-line 142, and a second engaging tab cutout 144 defined by cut-line 146. Side panels 104 and 106 further comprise access cutouts 148. As explained below, first engaging tab cutout 140 and engaging tab 22 together form an embodiment of a means for locking, while second engaging tab cutout 144 and engaging tab 22 together form an embodiment of a means for stopping.

[00036] With regard to assembly, the blank 102 is folded and connected using conventional techniques to create the outer sleeve 100, best shown in FIG. 1 as a slip case defining a void 150. One sequence of folding and connecting the blank 102 is as follows, with reference to the visible side of the illustrated blank 102 as the face and the opposite side as the back. Extension panel 120 is folded back along transverse fold-line 124b. Side panel 108 is then folded along longitudinal fold-lines 124a under the side panels 106, 104 and positioned under panel 104 so that the face of panel 108 may be affixed to the back of panel 104. In this embodiment, panel 108 is affixed to panel 104 so that the first engaging tab cutout 140 is immediately under the release button 130. In other words, in the illustrated embodiment the release button 130 is unobstructed by any solid surface of panel 108. End panels 116, 118 are folded inwardly so that the face of one end panel may be affixed to the back of the other.



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[00037] Generally speaking, items are placed within inner tray 12, 26 and then the combined card 10 and tray 12, 26 is inserted into the void 150 of outer sleeve 100. In the example of drug delivery devices holding unit doses, the illustrated Unit Dose Packaging System (UDPS) secures these devices until they are retrieved for use. In practice, items are placed within the inner tray 12, 26 and then the various panels and tabs are folded before the combined card 10 and tray 12, 26 is inserted into the outer sleeve 100. For purposes of teaching and not limitation, the following folding sequence is described. Top panel 20 is folded so as to cover the tray 12, 26 and orient the spine panel 18 adjacent to a side of the tray. Tab 22 is folded inwardly so that the face of tab 22 is proximate to the face of base panel 16. With the card 10 folded as described, the combined card 10 and tray 12, 26 is inserted into the void 150 of outer sleeve 100 through the open end, starting with the edge formed by fold-line 24b and with the tab 22 receivingly aligned with release button 130, as illustrated in FIG. 5. The card 10 with inner tray 12, 26 is then fully inserted into the outer sleeve 100, to a fully closed position.

[00038] With continued reference to FIG.1, and as understood by those skilled in the art, spring tension created by the inwardly folded tab 22 causes the tab edge 154 to contact the interior side of panel 108. Two particular points of contact along the interior side will be noted. From the fully closed position, the engagement of tab edge 154 with the internal edge 156 of cutout 140 at the locking position A provides a child-resistant feature. From a fully opened position, the engagement of the tab edge 154 with the interior of the folded extension panel 120 at the stopping position B provides a spill-resistant feature. The cutout 144 may be shaped to efficiently engage tab edge 154. As illustrated, cutout 144 provides a semi-circular concave profile when panel 120 is folded, which engages well with the semi-circular convex profile of tab edge 154. As understood by those skilled in the art, these engaging profile shapes are merely a design choice and not a limitation of the present invention. It will be understood that an embodiment of the UDPS may be constructed without either or both of the child-resistant or spill-resistant features.

[00039] In the illustrated embodiment the locking feature includes the release button 130, cutout 140, and cooperatively engaging tab 22. The spring tension created by the folded tab 22 causes the tab edge 154 to engage the internal edge 156 of cutout 140. With the tab 22 and internal edge 156 engaged, the inner tray 12, 26 is locked within the outer sleeve 100 and cannot be accessed. This means for locking creates a child-resistant feature. As illustrated, internal edge 156 has a semi-circular convex profile that engages well with the semi-circular convex profile of tab edge 154. To unlock the child-resistant feature of this embodiment and

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**CLAIMS**

**We claim:**

1. A device for receiving and securing an item, the device comprising a slide card (10) having an engaging element (22) including a first engaging edge (154) and a tray receiving area (14), a preformed tray (12) configured to receive and hold a portable item (30, 32) which tray is attached to the tray receiving area, an outer sleeve (100) configured to receive the slide card and attached tray and comprising a plurality of side panels (104, 106, 108), wherein a first side panel (108) is configured to be in face contacting relationship with a second side panel (104), an extension panel (120) hinged to an edge of the first side panel adjacent the third side panel (106), wherein an aperture (144) common to both of the first side panel the first side panel and the extension panel sized and arranged such that when the extension panel is folded inwardly of the outer sleeve the aperture forms a second engaging edge complementary to the first engaging edge, to prevent detachment of the slide and form the outer sleeve.
2. The device of claim 1, wherein the apparatus comprises a locking element configured to connect with the engaging element at a locking position and a release element integral to said outer sleeve, configured to disconnect said engaging element from said locking element to permit the slide card to be at least partially withdrawn from the outer sleeve.
3. The device of claim 1, wherein said second material is constructed of a first material and said tray is constructed of a second material.
4. The device of claim 3, wherein said second material is plastic.
5. The device of claim 1, wherein said engaging element is positioned on said tray.
6. The device of claim 1, wherein tray comprises at least one receiving recess configured to receive and hold said portable item.
7. The device of claim 1, wherein said outer sleeve further comprises an interior aperture configured to connect said engaging element at a stopping position.
8. A device for receiving and holding an item, comprising:

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a slide card constructed of a first material, comprising at least a first panel and at least one tray receiving area located on said first panel;

at least one pre-formed tray constructed of a second material and comprising at least one receiving recess, attached to said card at said tray receiving area; and,

an outer sleeve defining a void, comprising an open end configured to permit said card and attached tray to translate in and out of said void.

9. The device of claim 8, wherein said slide card further comprises an engaging element connected to at least one of said first panel and said tray.

10. The device of claim 9, wherein said outer sleeve further comprises a locking element configured to releasably connect to said engaging element at a locking position.

11. The device of claim 10, wherein said outer sleeve further comprises a release configured to disconnect said engaging element from said locking element.

12. The device of claim 11, wherein said outer sleeve further comprises a stopping element configured to connect to said engaging element at a stopping position.

13. The device for receiving and securing an item, comprising:  
a slide card comprising means for engaging and at least one tray receiving area;  
at least one pre-formed tray, attached to said tray receiving area, configured to receive and hold at least one portable item;  
an outer sleeve defining a void configured to receive said card and attached tray, comprising an open end and means for locking said means for engaging; and,  
means for releasing, integral to said outer sleeve, configured to disengage said means for engaging from said means for locking.

14. The device of claim 13, of claim 12, wherein said means for engaging comprises an element positioned on at least one of said card and said tray configured to cooperatively connect with said means for locking.

15. The device of claim 14, wherein said means for locking comprises an element positioned within said void configured to cooperatively connect with said means for engaging.

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16. The device of claim 15, wherein said means for releasing comprises a mechanism positioned along the exterior of said outer sleeve and proximate to said locking element.

17. The device of claim 13 further comprising a means for stopping.

18. A foldable tray card formed of contiguous panels, comprising:  
an engaging panel defined by a first edge and spaced apart hinge;  
a second panel defined by said hinge and a spaced apart second edge;  
a tray integral to said second panel;  
at least one receiving recess located within said tray, configured to receive and hold an item; and,  
a third panel hingedly attached to at least one of said second edge and said tray; configured to fold over and cover said item.

19. The device of claim 18, wherein said panels and said tray are constructed using a thermo-forming process.

20. The device of claim 17, wherein said panels and said tray are constructed using an injection molding process.

21. A method of resisting access to an item, comprising the steps of:  
providing a slide card comprising a base panel;  
attaching a pre-formed tray comprising at least one receiving recess to said base panel;  
providing a means for engaging associated with at least one of said card and said tray;  
placing an item in said receiving recess;  
providing an outer sleeve with an open end and adjacent void, said sleeve further comprising a means for locking;  
aligning said card with said open end;  
orienting said means for engagement with said means for locking; and  
inserting said card and tray fully into said void;  
causing said means for engaging and said means for locking to releasably connect.

22. The method of claim 20, wherein said step of providing an outer sleeve further comprises providing an outer sleeve having a means for releasing, said means for releasing configured to disconnect said means for engaging and said means for locking.

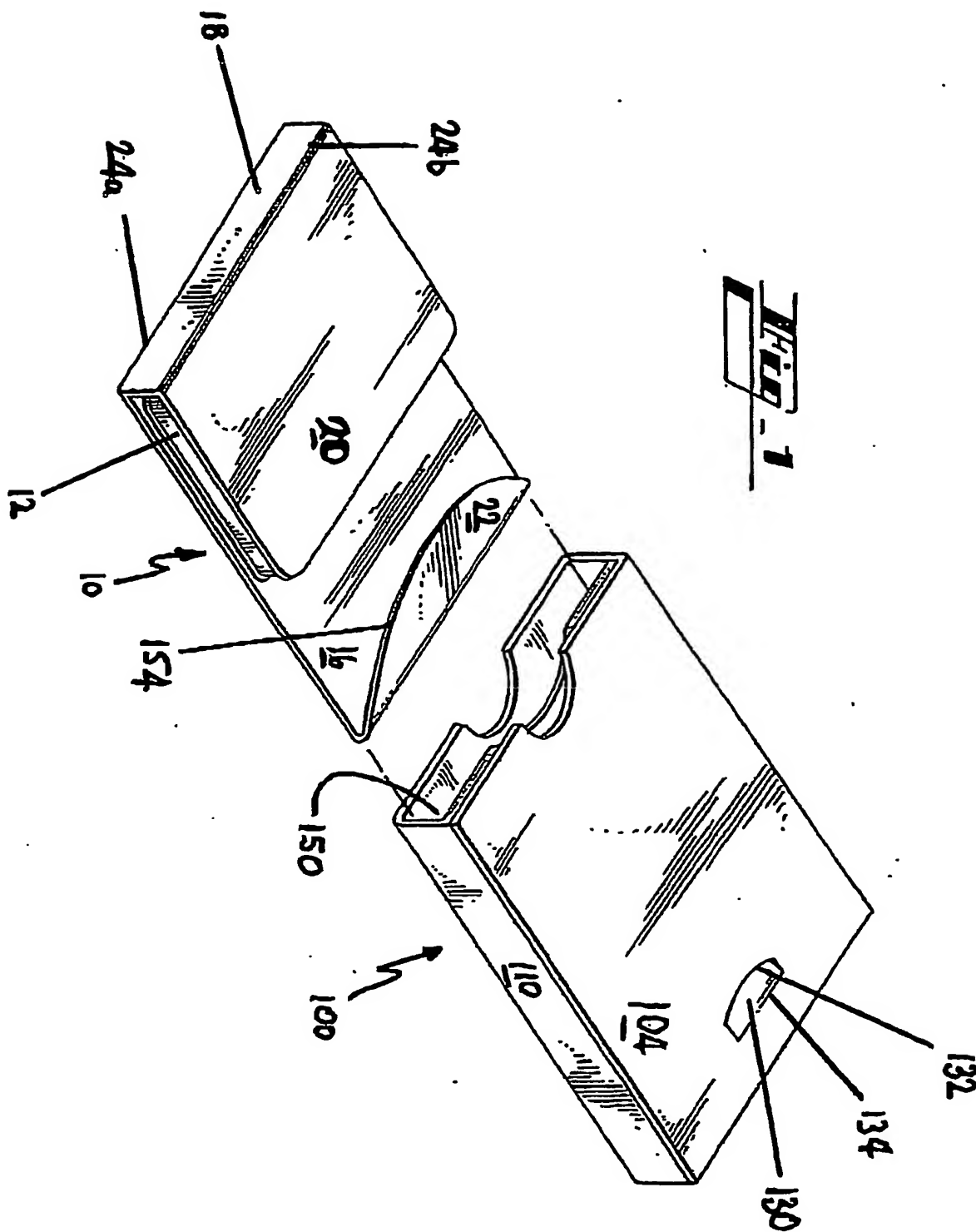
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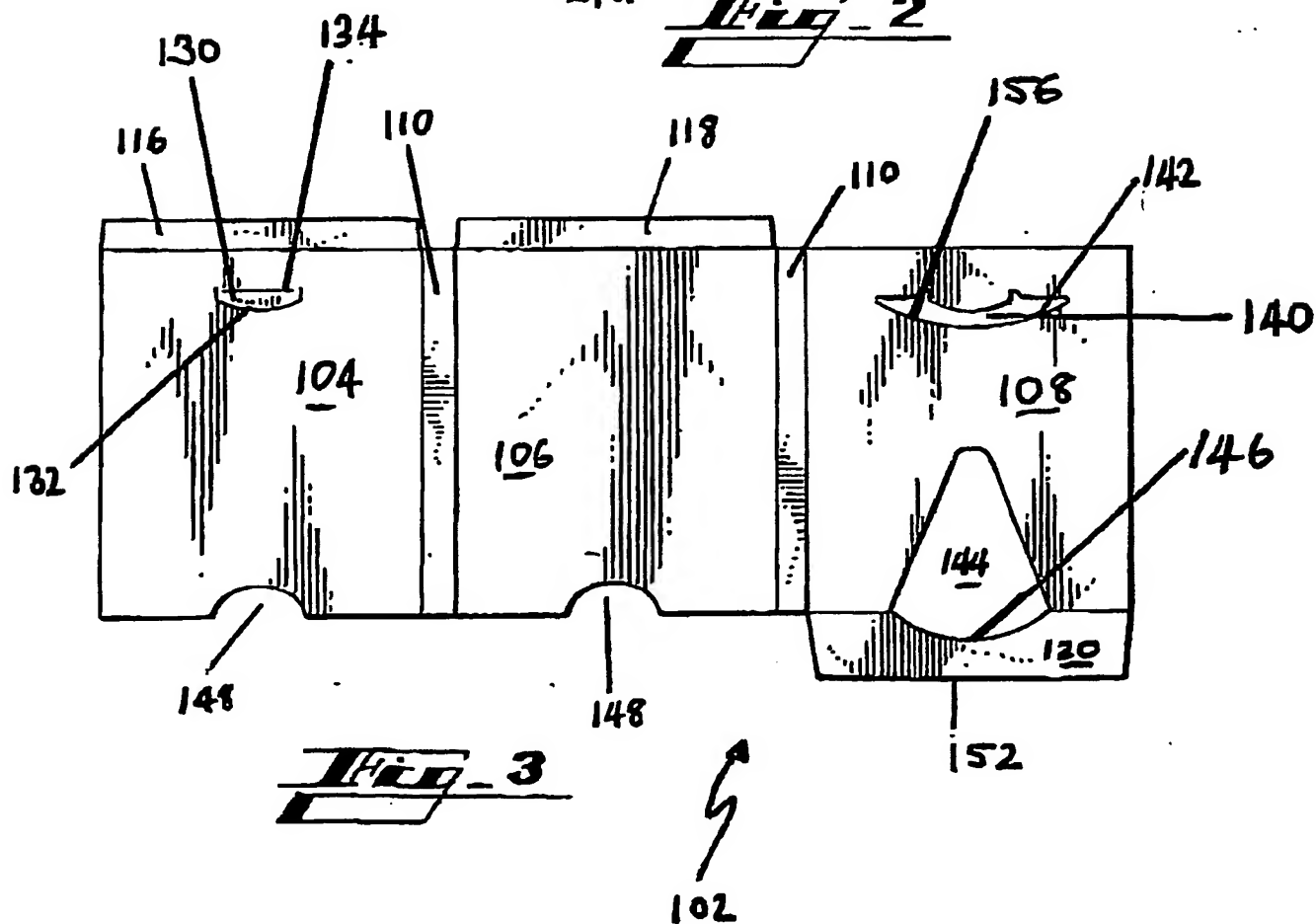
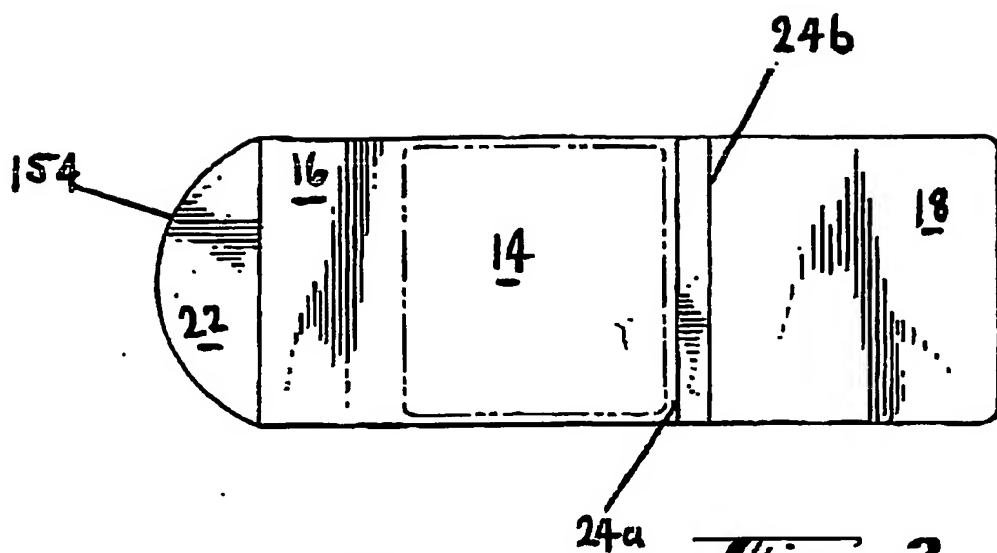
23. The method of claim 21, further comprising the step of manipulating said means for releasing to withdraw said tray at least partially from said void.

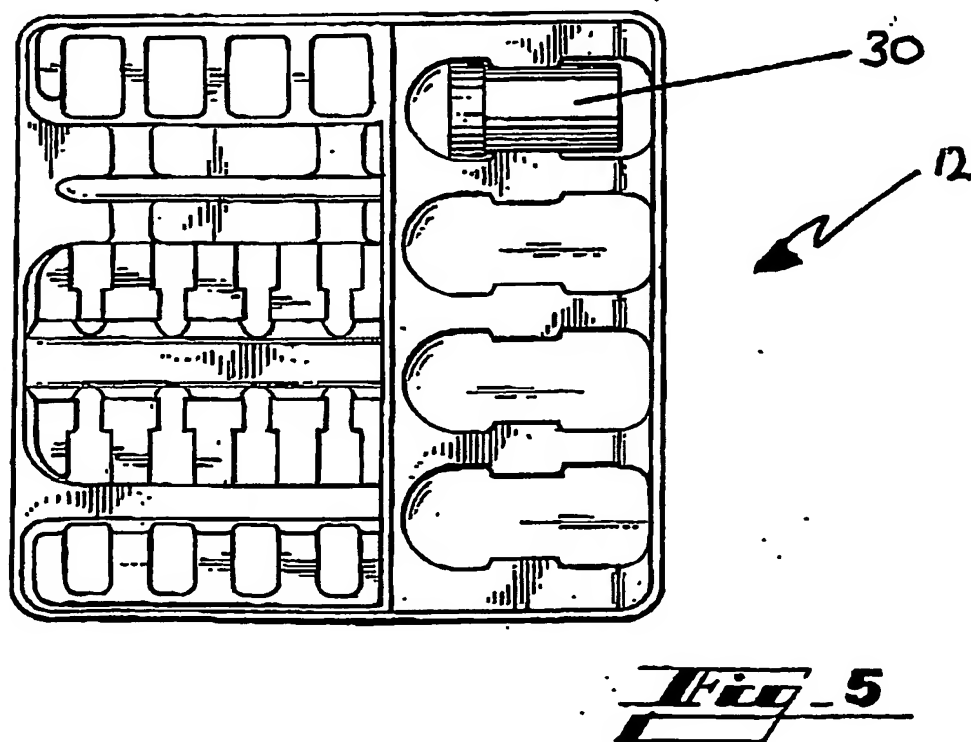
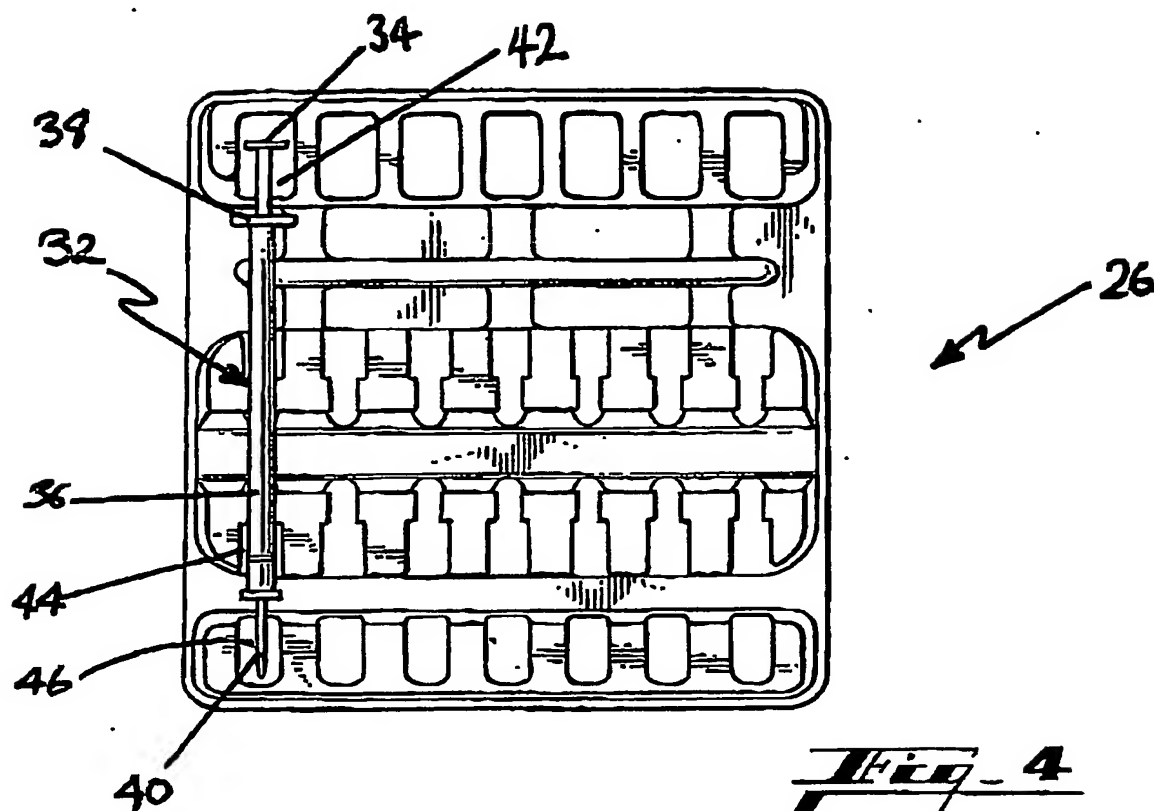
24. The method of claim 22, further comprising the step of withdrawing said item from said recess.

### ABSTRACT OF THE DISCLOSURE

Taught herein is a package for holding and storing various types of portable items. A pre-formed tray (12, 26) is configured to receive and store portable items of any size and shape. The tray is attached to a slide card (10), loaded with the items, and inserted into an outer sleeve (100). Receiving recesses (42, 44, 46, 48) hold the items in the tray. An engaging element (22) integral to the card or tray cooperatively engages locking elements and stopping elements (108, 120) integral to the outer sleeve. The cooperative engagement of the elements provides a child-resistant feature and a spill-resistant feature. A release element 130 disengages the child-resistant feature.









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